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EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DOMINIC P. BEHAN and DEREK T. CHALMERS

Appeal 2011-009250
Application 09/060,188
Technology Center 1600

Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON REHEARING

This is an appeal under 35 U.S.C. § 134. Appellants request rehearing of our decision dated February 2, 2012. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The following claim is representative and reads as follows:

69. A method for directly identifying a non-endogenous candidate compound as a compound that stimulates an endogenous G protein coupled receptor (GPCR) or reduces the activity of an active receptor state of an endogenous GPCR, wherein an endogenous ligand for said endogenous GPCR has not been identified, said method comprising the steps of:

(a) obtaining a constitutively activated form of said endogenous GPCR, wherein said constitutively activated GPCR comprises a mutation in its amino acid sequence that increases its constitutive activity relative to said endogenous GPCR;

(b) contacting the non-endogenous candidate compound with said constitutively activated GPCR;

(c) analyzing whether said non-endogenous candidate compound is a compound that stimulates said endogenous GPCR or reduces the activity of an active receptor state of said endogenous GPCR, by measuring the ability of the candidate compound to stimulate or inhibit functionality of said constitutively activated GPCR, respectively.

Cited References

The Examiner relies on the following prior art references:

Feldman, Ross D., *Deactivation of Vasodilator Responses by GRK2 Overexpression: A Mechanism or the Mechanism for Hypertension*?, 61Mol. Pharmacol 707-709 (2002).

Janigro, Damir, *Gene Expression in Temporal Lobe Epilep*sy, 8 Epilepsy Currents 23-24 (2008).

Liao et al., *STRL33, A Novel Chemokine Receptor-like Protein, Functions as a Fusion Cofactor for Both Macrophage-tropic and T Cell Line-tropic HIV-1*, 185 The Journal of Experimental Medicine 2015-2023 (1997).

Alkhatib, Ghalib et al., *A new SIV co-receptor, STRL33*, 388 NATURE 238 (1997).

Farzan et al., *Two Orphan Seven-Transmembrane Segment Receptors Which Are Expressed in CD4-positive Cells Support Simian Immunodeficiency Virus Infection*, 186 J. Exp. Med. 405-411 (1997).

Press Release 1, Exhibit E, Arena Pharmaceuticals, Inc.

Press Release 2, Exhibit F, file://C:\Documents and Settings\DCS\Desktop\AREN-001CIP draft\Press Releases NBIX.htm (2007).

Grounds of Rejection

1. Claims 34, 45-52, 61, 62, 69, 77, 79 and 81 are rejected under 35 U.S.C. § 101 for lack of utility.

2. Claims 34, 45-52, 61, 62, 69, 77, 79 and 81 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement.

FINDINGS OF FACT

The findings of fact are set forth in the Answer at pages 3-8. Highlighted facts follow.

1. An orphan receptor is defined on page 20 of the Specification, as "an endogenous receptor for which the endogenous ligand specific for that receptor has not been identified or is not known." (*See also* Ans. 5.)

2. "The previously submitted references provide evidence of identification of an endogenous, naturally occurring molecule specific for each of STRL33, gpr1, and gpr15. Farzan et al (1998; Exhibit B) teaches that "The gp120 [viral] glycoprotein binds the CD4 molecule, following which the gp120- CD4 complex binds one of the members of the chemokine receptor subgroup of seven transmembrane segment (7-TMS) receptor" (pg 405). Farzan et al further identifies the7-TMS receptors gpr1 and gpr15 as "coreceptors for SIV [simian immunodeficiency virus]". Thus, Farzan et al teach that the gp120-CD4 complex binds to each of gpr1 and gpr15. Farzan et al do not teach whether or not the CD4 portion of the complex binds directly to

gpr1 or gpr15, but the term "specific" encompasses either direct or indirect binding through a second molecule (i.e., the gp120-CD4 complex "specifically" binds to gpr1 or gpr15 as opposed to binding to most other cell surface molecules). The CD4 component of this complex is a material which a mammal naturally produces, and thus meets the definition of endogenous in the instant specification. Thus, Farzan et al teach an endogenous, naturally occurring molecule (CD4) specific for gpr1 and gpr15. Thus, gpr1 and gpr15 are not receptors as defined by the instant claims."

(Ans. 13-14.)

3. "Similarly, Liao et al (1997; Exhibit B) teaches that STRL33 is a cofactor for HIV entry in cells expressing CD4; thus CD4 is an endogenous ligand for STRL33. Thus, at the time of filing of the instant application neither of STRL33, gpr1 or gpr15 was a receptor as encompassed by the instant claims." (Ans. 14.)

PRINCIPLES OF LAW

Where the invention is a process, the product resulting from that process must have utility in order for the process to have utility. *Brenner v. Manson*, 383 U.S. 519, 536 (1966).

Evidence of utility must be commensurate in scope with the claimed invention *In re Buting*, 418 F.2d 540, 543 (CCPA 1969).

"It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Angstadt*, 537 F.2d 498, 502-03 (CCPA 1976). However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill in the art how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed

> utility." *In re Vaeck*, 947 F.2d 488, 496, (Fed. Cir. 1991) (footnote omitted).
>
> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 183 USPQ 288 (C.C.P.A. 1974)

Discussion

ANALYSIS

Appellants argue that the Board's statement in the Decision that the receptors of Liao, Alkhatib and Farzan "are not receptors within the scope of the claims because their function is known" is clearly incorrect. Appellants argue that the fact that the receptors had a known function was irrelevant to whether they were orphan receptors. Rehearing 2.

Our decision agreed with the fact finding and responses to Appellants' arguments set forth in the Answer. (Decision 6.) We have repeated the fact finding from the Decision above, showing that a gp120-CD4 complex was a ligand for the receptors of Liao, Alkhatib and Farzan. (Ans. 14-15.) Thus, the decision could have more artfully stated that because an endogenous ligand, CD4, was known for the receptors of Liao, Alkhatib and Farzan, they

are not orphan receptors within the scope of the claim. Thus, Appellants' argument does not change the outcome in the present case.

Moreover, evidence of utility must be commensurate in scope with the claimed invention. The present claims broadly encompass orphan receptors with no known function and with no known ligand. To be useful, or have utility under the law, a composition must have a substantial and specific function. Even though Appellants claim a method, the product resulting from that method must also have a substantial utility that provides a currently available specific benefit in order for the process to have utility under § 101. *Brenner v. Manson*, 383 U.S. 519, 536 (1966). One of ordinary skill in the art does not know specifically what the receptors do within the scope of the claims, and therefore a compound identified according to the claims would not have a substantial and specific utility; thus the Specification does not teach those of ordinary skill in the art how to use the invention as broadly as it is claimed.

Thus, for the reasons of record, the Specification does not demonstrate a useful function for a compound identified using an orphan GPCR encompassed by the claims. The Specification does not teach any specific and substantial pharmaceutical use for an agent that modulates a receptor in absence of the knowledge of its natural ligand. "[T]he identification of such 'pharmaceutical' use represents 'further research' that must be completed in order for the invention to prove useful at some future date." (Ans. 11; Decision 7.)

CONCLUSION OF LAW

The Request for Rehearing is denied.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

REHEARING DENIED

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